IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of RICHARD SMITH, Deceased,	)	
Plaintiff,	)	
v.	)	**Case No. 3:05-0444**
	)	**Judge Trauger**
PFIZER INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM

Among the numerous motions *in limine* pending before the court are two motions *in limine* filed by the plaintiff (Docket Nos. 89 and 92) and two motions *in limine* filed by the defendants (Docket Nos. 115 and 118). These motions have been fully briefed, and the court's findings are discussed below.

BACKGROUND

On May 13, 2004, 79-year-old Richard Smith ("Smith") committed suicide.[1] Two months earlier, Smith had filled a prescription for the medication Neurontin, which is manufactured by defendants Pfizer Inc. and Warner-Lambert Co. LLC (collectively, "Pfizer" or "defendants"). Smith's widow, plaintiff Ruth Smith, alleges that Smith's ingestion of Neurontin caused his suicide.

[1] Unless otherwise noted, the facts are drawn from the parties' submissions and the court's previous Memorandum regarding the defendants' Motion for Summary Judgment. (Docket No. 63.).

In the years leading up to his death, Smith suffered from chronic joint and spine conditions that caused him severe pain and required numerous surgeries. Smith's orthopedic surgeon, Dr. Edward Mackey, prescribed 300 mg of Neurontin, twice daily, in an effort to treat Smith's chronic pain. In addition to filling that prescription, Smith had also received several sample packages of Neurontin from a nurse in Dr. Mackey's office. But throughout March and April of 2004, Smith continued to experience excruciating pain, and on May 13, he shot himself.

Although Neurontin has been approved by the FDA to treat epilepsy and post-herpetic neuralgia, doctors frequently prescribe it for the "off-label" usage of treating pain. The plaintiff alleges that the defendants aggressively marketed these properties of Neurontin, and in May 2004, Warner-Lambert Co. LLC pleaded guilty to charges that it marketed the drug for off-label use in 1995 and 1996. Currently, the vast majority of Neurontin prescriptions are written for off-label purposes.

During visits to Dr. Mackey's office, Pfizer sales representatives promoted Neurontin's ability to treat neuropathic pain, but they failed to disclose that the drug may cause depression and suicidality in patients. The plaintiff alleges that the defendants were aware of these side effects.

The plaintiff originally filed suit in Tennessee state court. Pfizer removed to this court in June 2005, and in July 2005, the case was transferred to the District of Massachusetts (the "MDL court"), pursuant to an order from the Judicial Panel on Multidistrict Litigation. There, the case underwent consolidated pretrial proceedings with similar cases in MDL No. 1629, *In re Neurontin Marketing, Sales Practices and Products Liability Litigation*. The case was remanded

to this court on November 9, 2009. (Docket No. 10.)

The plaintiff's Amended Complaint asserts claims for: (1) negligence; (2) breach of warranty; (3) strict liability, or products liability; (4) fraud; and (5) violation of Tennessee consumer protection statutes. (D. Mass, No. 1:04-10981, Docket No. 1209.) The MDL court dismissed the plaintiff's claims for affirmative fraud, fraudulent concealment premised on the defendants' national marketing and advertising campaign, breach of express warranty, and violation of consumer protection statutes. *In re Neurontin Mktg.*, 618 F. Supp. 2d 96, 114 (D. Mass. 2009); (D. Mass, No. 05-11515, Docket No. 10 at 2). This court denied the defendants' subsequent Motion for Summary Judgment. (Docket No. 64.) Thus, the following claims have survived for trial: (1) negligence; (2) breach of implied warranty; (3) products liability for failure to warn; and (4) fraudulent concealment that is not premised on a national marketing campaign.

ANALYSIS

The parties have filed numerous motions *in limine*. This Memorandum will address four of these motions.

I. The Plaintiff's Motion to Exclude Testimony of Sheila Weiss Smith, Ph.D. (Docket No. 89)

The plaintiff argues that the court should exclude the testimony of the defendant's expert witness Sheila Weiss Smith, Ph.D., pursuant to Federal Rule of Evidence 702. This motion will be denied.

Rule 702 states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill,

> experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Thus, in evaluating proposed expert testimony, the court plays a "gatekeeping" role, in which it must evaluate, based on all of the circumstances, the relevance and reliability of all expert testimony and whether the testimony offered is "scientific" or not. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999); *see also Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 593-94 (1993).

The defendants have offered Weiss Smith as an expert in epidemiology, pharmacoepidemiology, and pharmacovigilance. (Docket No. 143 at 1.) Pharmacoepidemiology is the study of the use and effects of medical products, including drugs, in human populations. (*Id.* at 6.) It is a branch of epidemiology, which is a field that deals with questions of general causation by examining evidence of risk of disease within groups of individuals. Pharmacovigilance, as defined by the FDA, refers to scientific and data-gathering activities related to the detection, assessment, and understanding of adverse events. (*Id.* at 7.) Weiss Smith's credentials include her position as a Professor in the School of Pharmacy and Epidemiology & Preventative Medicine at the University of Maryland-Baltimore and her experience in serving as a voting member on a number of FDA advisory committees.

Weiss Smith's report and supplemental report focus on her analysis of post-marketing adverse data and clinical trial data regarding Neurontin. Specifically, she analyzed clinical trial data that was prepared by Pfizer and submitted to the FDA, as well as data from the FDA's

spontaneous reporting system database, AERS, which catalogs adverse event reports. These reports are submitted when patients suffer an adverse event that might have been caused by a drug. Dr. Weiss Smith generally concluded that: (1) the data shows that there was no statistical signal indicating a link between Neurontin and patients' suicides or suicide attempts; (2) the data does not support a causal relationship between Neurontin and suicide; and (3) Neurontin's product labeling accurately reflected this information. Weiss Smith opined that the analysis of the AERS data by the plaintiff's experts is flawed, and she concluded that the FDA's 2008 meta-analysis regarding the side effects of anti-epilepsy drugs was methodologically flawed and does not support the conclusion that Neurontin causes suicide.

The plaintiff's main argument is that Weiss Smith has no expertise in (1) making clinical assessments, (2) writing FDA-compliant drug labels, (3) suicidology, or (4) pharmacovigilance practices, and that she should be barred from opining on those subjects. (Docket No. 90 at 4-7.) But the court finds that Weiss Smith's opinions all arise directly from her area of undisputed expertise – pharmacoepidemiological analysis. Nothing in Weiss Smith's analysis required her to exercise any kind of clinical judgment or required that she possess expertise in suicidology or FDA labeling. Furthermore, the defendants do not plan to have Weiss Smith testify regarding the adequacy of defendants' pharmacovigilance practices or conduct. (Docket No. 143 at 2, 7.)

The plaintiff contends that Weiss Smith's methodology in searching the AERS database was flawed, making her testimony inadmissible. Weiss Smith's report and supplemental report focus largely on her analysis of whether the post-market adverse event reports should have alerted the defendants that Neurontin might cause suicide-related side effects. She essentially

concluded that suicide-related adverse event reports did not occur with enough frequency to raise any red flags. One necessary step in this analysis was deciding which search terms to use when searching the AERS database for adverse event reports. Weiss Smith searched the database only for "completed suicide" and "suicide attempt," whereas the plaintiff's experts also included broader terms like "suicide ideation" and "self-injurious behavior." The plaintiff claims that Weiss Smith's failure to include the latter terms invalidate her methodology.

But a dispute over the exact contours of the search terms does not affect the validity of the underlying methodology of the analysis, and it does not render Weiss Smith's analysis unreliable. The defendants point out that Weiss Smith chose those search terms because she was focused on finding adverse events that unambiguously meet the regulatory definition of "serious." *See* 21 § C.F.R. 314.80(a) (defining serious cases to include those that lead to death, hospitalization, or serious disability). The plaintiffs can address the exclusion of certain search terms when they cross-examine Weiss Smith. Furthermore, contrary to the plaintiff's suggestions, the decision regarding search terms did not require any special expertise in suicidology. Accordingly, this is not a basis to exclude Weiss Smith's testimony.

The plaintiff argues that Weiss Smith destroyed her underlying data, making it impossible to recreate her calculations. (Docket No. 90 at 15.) But the defendants point out that Weiss Smith used a commercially available program, called QScan, to search and analyze the AERS data. (Docket No. 143 at 14.) After downloading the voluminous source data for a search, she created a summary spreadsheet and deleted the source data. Her searches were reproducible in QScan. (*Id.*) Furthermore, the parties stipulated in February 2009 that their

respective experts were capable of recreating each other's AERS searches. (*See* Docket No. 144, Ex. 9.) Because the plaintiffs could have simply recreated Weiss Smith's searches, this provides no basis to exclude her testimony.

The plaintiff argues that Weiss Smith did not review sufficient materials. (Docket No. 90 at 18.) But she reviewed the same submissions from Pfizer that the FDA relied upon when it analyzed the possible suicide-related side effects of anti-epileptic drugs. *See* Fed. R. Civ. P. 703 (allowing expert testimony based on data "of a type reasonably relied upon by experts in the particular field"). She also reviewed post-market data. If the plaintiff wishes to argue that Weiss Smith should have analyzed some other set of additional data, the plaintiff may cross-examine her on that point.

The plaintiff also argues that math mistakes, typographical errors, and arguably misleading citations contained in Weiss Smith's report merit the exclusion of her testimony. (Docket No. 90 at 12-18.) While these might undercut Weiss Smith's credibility, they do not affect the admissibility of her testimony. *See, e.g.*, *Baldwin v. Bader*, 539 F. Supp. 2d 443, 446 (D. Me. 2008) (holding that an expert's "miscalculations go to the weight, not the admissibility, of his opinions") (citing *United States v. Bonds*, 12 F.3d 540, 561 (6th Cir. 1993)). The plaintiff is free, of course, to highlight these errors during cross-examination.

The plaintiff's other arguments provide no basis for excluding Weiss Smith's testimony. Accordingly, the plaintiff's motion will be denied.

II. The Plaintiff's Motion to Strike the Deposition Testimony and Affidavit of Cynthia McCormick and to Preclude the Defendants from Using the Deposition of Charles Taylor at Trial (Docket No. 92)

The plaintiff seeks to exclude the deposition testimony of defense witness Dr. Cynthia McCormick and to preclude the defendants from using the deposition of their expert Dr. Charles Taylor at trial. This motion will be denied.

Cynthia McCormick is a medical doctor who worked for the FDA from July 1991 to October 2002. During the first six years of her employment at the FDA, she was a medical officer. Her responsibilities included reviewing investigational new drug applications, and she worked on the new drug application for Neurontin. (Docket No. 141 at 2.) Later, she became a divisional director and was involved in the FDA's approval of Neurontin for treatment of post-herpetic neuralgia. McCormick is currently a consultant.

McCormick is perhaps most relevant to this litigation because, during the FDA's clinical review of Neurontin, she stated that "depression, while it may not be an infrequent occurrence in the epileptic population, may become worse [when the patient takes Neurontin]" and that this was one of the "more serious events that may limit the drug's widespread usefulness." (Docket No. 93 at 4.) Part of her current testimony is devoted to explaining why this statement is not inconsistent with her affidavit, which stated that she never concluded that Neurontin increased the risk of suicide-related behavior.

The plaintiff contends that the defendants are using McCormick as an expert witness. Federal Rule of Evidence 701 "foreclose[s]" lay witnesses who have not been qualified as experts from testifying "based on scientific, technical, or other specialized knowledge." *United States v. White*, 492 F.3d 380, 400 (6th Cir. 2007). Instead, such testimony is expert testimony covered by Rule 702. *Id.* Federal Rule of Civil Procedure 26(a)(2) provides that expert

witnesses who give scientific or technical testimony under Rule 702 generally must file a written report and that the party offering the expert witness must comply with certain disclosure requirements. The defendants did not follow Rule 26(a)(2)'s requirements with regard to McCormick, who did not produce a written report. The plaintiff argues that this precludes the defendants from offering her testimony at trial.

The court finds that, as a fact witness who was involved in the events underlying this case, McCormick is allowed to testify regarding her personal involvement in the drug application process and the opinions she held at that time. The defendants point out that her testimony involves her "personal knowledge as to what evidence was considered by the FDA during the review process." (Docket No. 141 at 4.) This is borne out by the portion of the deposition transcript that is attached to the defendants' response brief; the questions by the defendants' counsel dealt with McCormick's personal experience at the FDA. For example:

> While you were at the FDA, to the best of your knowledge, did any individual within the FDA or the FDA generally, ever conclude that Neurontin is associated with or increases the risk of depression or any type of suicidal thinking or behavior? . . .
>
> If the FDA had concluded that Neurontin increased the risk of depression or any type of suicidal thinking or behavior, what based on your experience would the FDA have done?

(Docket No. 142, Ex. 1 at 108-09).

The plaintiff argues that, in order for McCormick to explain her 1992 statement regarding Neurontin and depression, she will need to testify based on scientific or technical knowledge.[2]

[2] The plaintiff also argues that, because McCormick's deposition testimony contradicts the statement that she made in 1992, she is clearly acting as an expert witness. (Docket No. 93 at

(Docket No. 93 at 4.) The court declines to find that this explanatory testimony requires McCormick to file a written report or qualify as an expert under Rule 702. First, it would be absurd to require a fact witness, who is testifying to explain a statement she made during the events underlying the case, to qualify as an expert. Second, the Sixth Circuit has noted that the distinction between lay testimony and expert testimony "is far from clear in cases where . . . a witness with specialized or technical knowledge was also personally involved in the factual underpinnings of the case." *White*, 492 F.3d at 401. The court believes that, in this case, McCormick is not offering expert testimony.

Furthermore, "Rule 26(a)(2)(B) by its terms provides that a party needs to file an expert report from a [witness] only if that [that witness] was 'retained or specially employed to provide expert testimony.'" *Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 869 (6th Cir. Ohio 2007) (quoting Fed. R. Civ. P. 26(a)(2)(B)). In discussing a witness who was a treating physician, the Sixth Circuit held that the physician was *not* retained to provide expert causation testimony, as covered by Rule 26, if he formed his opinions on causation at the time he treated the patient. *Id.* Here, McCormick's testimony is analogous to that of a treating physician. Even if her testimony involves scientific or technical knowledge, McCormick is testifying regarding opinions that she formed when she worked for the FDA. Accordingly, she was not required to furnish an expert report.

The plaintiff also argues that McCormick is an expert witness because she has been

---

3.) But this supposed inconsistency affects to her credibility, not whether she is providing expert testimony. Her status as a fact witness is also unaffected by the fact that the defendants' counsel was involved in drafting her affidavit.

compensated by the defendants. At her deposition, McCormick testified that she was being paid her usual consulting fee of $500 per hour for the time spent testifying and preparing for the deposition. She also testified that, several months earlier, she had submitted a bill for $17,000 to the defendants for time spent preparing her affidavit. But this, standing alone, does not make her an expert witness. It is not necessarily improper for a party to pay a fact witness if the money compensates the witness, at his or her professional rate, for lost time. *See Prasad v. MML Investors Servs.*, No. 04 Civ. 380, 2004 U.S. Dist. LEXIS 9289, at *16 (S.D.N.Y. May 24, 2004) (noting that federal courts "are generally in agreement that a [fact] witness may properly receive payment related to the witness' expenses and reimbursement for time lost associated with the litigation"). An ABA ethics opinion allows parties to pay witnesses for their "loss of hourly wages or professional fees." ABA Ethics Op. 96-402 (Aug. 2, 1996); *see also TBC Corp. v. Wall*, 955 S.W.2d 838, 842 (Tenn. Ct. App. 1997) (refusing to exclude the testimony of the defendants' fact witness even though "the defendants had paid the sum of $5,000.00 in addition to a contingency arrangement of $35,000.00, dependant upon the outcome of the trial").

According to the defendants, their payments to McCormick compensated her for her time spent preparing to provide her affidavit and deposition testimony. (Docket No. 141 at 5.) The court finds that, although these payments certainly affect McCormick's credibility, they do not render her an expert witness.

Finally, the plaintiff argues that the court should not allow the defendants to use Charles Taylor's deposition testimony at trial, absent a showing that he is unable to attend the trial. A party may use the deposition of an "unavailable witness" if the court determines that the witness

cannot testify because of illness or infirmity. Fed. R. Civ. P. 32(a)(4)(C). The defendants claim that they currently intend to have Taylor, who lives in Michigan and is undergoing treatment for leukemia, testify in person at trial.[3] (Docket No. 141 at 7.) This makes the plaintiff's motion premature. If circumstances change, the court can require the defendants to present evidence of Taylor's inability to travel at that time.

Accordingly, the plaintiff's motion will be denied.

III. The Defendants' Motion to Exclude Evidence of Marketing or Advertising Materials and Conduct and Other Litigations (Docket No. 115)

The defendants argue that the court should exclude the plaintiff's "voluminous and wide-ranging testimonial and documentary evidence relating to Pfizer's marketing and advertising of Neurontin," (Docket No. 116 at 1), because it is irrelevant, unfairly prejudicial, and confusing, and because it would expand the scope of the trial. They also argue that the court should exclude evidence of other civil suits against the defendants. This motion will be denied.

The defendants correctly point out that there is no allegation that Smith's prescribing doctor ever saw material from a national marketing campaign or that such material influenced his decision to prescribe Neurontin to Smith. Accordingly, they argue, the marketing campaign has no relevance to the "learned intermediary doctrine," which applies to the plaintiff's products liability failure to warn claim. (*Id.* at 3-4.)

But the defendants' marketing efforts, which encouraged doctors to prescribe Neurontin

[3] Taylor is an employee of Pfizer. Presumably, this is why the defendants do not argue that they can use his deposition because he lives more than 100 miles away from the court. *See* Fed. R. Civ. P. 32(a)(4)(B).

for off-label uses, *is* relevant to the plaintiff's negligence claim. *See* Fed. R. Evid. 401. Specifically, the plaintiff's claim is premised on the defendants' duty to properly test and label the drugs that they sell and market. If a drug maker engages in an extended, coordinated campaign to increase a drug's off-label usage, a jury may find that the company breached its duty of care by failing to adequately ensure that the drug is safe for such usage. The plaintiff has alleged that the defendants were negligent in failing to sufficiently test the safety of Neurontin for off-label uses, which directly led to their failure to warn of the drug's suicide-related risks. Or, as the plaintiff states, her claim is that the defendants "were negligent and reckless in knowingly not performing adequate pharmacovigilance to ascertain whether the drug was safe for the off-label uses by the population for which they were promoting the drug off-label." (Docket No. 162 at 7-8.)

The defendants further argue that courts recognizing a duty to warn of risks associated with off-label use "have done so based upon the *foreseeability* of the off-label use, not whether the drug was *marketed* for off-label uses." (Docket No. 116 at 5.) "Pfizer does not contend that the prescription of Neurontin to treat Mr. Smith's pain was unforeseeable or that it constituted a misuse of the product." (*Id.* at 6.) Instead, "Pfizer argues that there was no duty to warn because there was not at the time of Mr. Smith's death any reliable evidence establishing a causal association between Neurontin and suicide." (*Id.*)

First, a coordinated marketing campaign endorsing off-label use obviously bears on "the foreseeability of off-label use" – it makes such use more likely. Second, the relevance of the evidence is not negated by the fact that the defendants concede that off-label use was, to some

degree, foreseeable. Finally, as explained above, a marketing campaign is relevant to whether the defendants' efforts to test Neurontin's safety for off-label uses were reasonable.

The defendants argue that evidence of Pfizer's marketing should be excluded as unduly prejudicial. Federal Rule of Evidence 403 provides that a court may exclude relevant evidence if the evidence's "probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. "A district court is granted 'very broad' discretion in determining whether the danger of undue prejudice outweighs the probative value of the evidence." *United States v. Mack*, 258 F.3d 548, 555 (6th Cir. 2001). The court is unpersuaded that the probative value of the defendants' marketing campaigns is outweighed by any potential unfair prejudice. Nor does the court believe that the plaintiff's introduction and the defendants' refutation of such evidence will be a waste of time or will unnecessarily prolong the trial.

The court also rejects the defendants' arguments that evidence of the national marketing campaign constitutes impermissible character evidence. Rule 404(b) provides that "[e]vidence of other crimes, wrongs, or acts is not admissible to prove the character of a person in order to show action in conformity therewith." Fed. R. Evid. 404(b). The rule does not apply, however, to "intrinsic" acts that are part of a single bad act; thus, "Rule 404(b) is not implicated when the other [bad acts are] part of a continuing pattern of illegal activity." *United States v. Barnes*, 49 F.3d 1144, 1149 (6th Cir. 1995).

Here, the coordinated marketing campaign is not a "prior bad act." Instead, it is an

ongoing act that forms the basis of the plaintiff's negligence claim. As the plaintiff states, "the national documents actually show a plan and scheme to circumvent the pharmacovigilance requirements of the FDA." (Docket No. 162 at 12.) Accordingly, the plaintiff may introduce evidence regarding the defendants' national advertising campaigns.

The defendants also seek to bar admission of evidence regarding other claims, actions, or legal proceedings related to Neurontin. (Docket No. 116 at 10-11.) It is possible that these suits are relevant to show notice to the defendants of possible safety problems with Neurontin. But the specifics of the proposed evidence is unclear – for example, the court does not know the number of lawsuits at issue, the specific subject matter of the suits, or when they were filed. Depending on these variables, it is possible that any probative value is outweighed by the risk of unfair prejudice.[4] *See* Fed. R. Evid. 403; *McLeod v. Parsons Corp.*, 73 Fed. Appx. 846, 854 (6th Cir. Tenn. 2003) (finding that "the potential for prejudice that would have accompanied this evidence [of previous lawsuits] would have substantially outweighed its probative value, and this evidence would have misled the jury"). Until the parties provide more specifics regarding the evidence at issue, the court cannot rule on this matter.

Accordingly, the defendants' motion will be denied.

IV. The Defendants' Motion to Exclude Testimony of Charles King (Docket No. 118)

The defendants argue that the court should exclude the testimony of plaintiff's marketing

[4] For example, lawsuits filed shortly before Smith's death would have limited probative value.

expert, Dr. Charles King III.[5] This motion will be denied.

King is an economist and has received a J.D. from Yale and a Ph.D. in economics from the Massachusetts Institute of Technology. He taught economics, including courses on marketing, at Harvard until 2003, and he has previously worked and published in the field of pharmaceutical marketing.

King's expert report examines characteristics of the prescription drug marketplace and explains, in that context, the goals and effects of the defendants' marketing efforts. In forming his opinions, he reviewed the defendants' internal documents, government records, sales and industry data, and scholarly studies. King's primary conclusion is that the defendants' off-label marketing campaign led to an increase in off-label prescriptions. (Docket No. 165, Ex. 1 ¶ 103.) In 1994, approximately 15% of Neurontin usage was for off-label purposes, whereas, in 2002, 94% of usage was off-label. (Docket No. 164 at 15.) King concluded that off-label marketing was a "significant" factor in this increase. (Docket No. 165, Ex. 1 ¶ 103.) He also concluded that, due to the characteristics of the market and the fact that doctors often rely on consulations with colleagues, even doctors who did not receive marketing materials were indirectly influenced by the marketing campaign. (Docket No. 165, Ex. 1 ¶¶ 80-87, 103.)

The defendants, broadly speaking, argue that King's testimony is irrelevant and is not

[5] Contrary to the plaintiff's argument, it does not appear that the defendants' motion to exclude King's testimony is untimely. The plaintiff cites a scheduling order that set a deadline for *Daubert* motions regarding expert reports addressing "general causation." (D. Mass, No. 1:04-10981, Docket No. 582 at 2.) Because King's testimony is not related to general causation (i.e., whether Neurontin does, generally speaking, cause suicide-related side effects), the deadline does not apply.

supported by proper methodology. Under Federal Rule of Evidence 702, a district court's task in assessing expert evidence is to determine whether the evidence "'both rests on a reliable foundation and is relevant to the task at hand.'" *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 915 (6th Cir. 2009) (quoting *Daubert*, 509 U.S. at 597). Generally, "[t]he district court must consider 'whether the reasoning or methodology underlying the testimony is scientifically valid.'" *Id.* (quoting *Daubert*, 509 U.S. at 592-93). But when deciding whether to admit expert testimony that relates to a social science, "the factors suggested in *Daubert* are not to be applied mechanically; rather, district courts are accorded wide latitude in determining the reliability of expert testimony." *United States v. Leblanc*, 45 Fed. Appx. 393, 399 (6th Cir. 2002); *see also United States v. Simmons*, 470 F.3d 1115, 1123 (5th Cir. 2006) (noting courts' discretion in admitting testimony regarding "areas of expertise, such as the 'social sciences in which the research, theories and opinions cannot have the exactness of hard science methodologies'"). The purpose of the court's gatekeeping role "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho*, 526 U.S. at 152.

First, the court finds that King's testimony is relevant and helpful to the jury. It is true, as the defendants point out, that King does not opine that Smith's prescription was directly related to the national off-label marketing campaign. But his testimony will assist the jury in placing the defendants' marketing campaign in context and will explain why the campaign was effective. King's testimony is relevant for the same reasons that evidence of the defendants'

marketing activities is relevant: It bears on (1) the defendants' knowledge that significant off-label use was foreseeable and (2) whether the defendants took sufficient steps to ensure the safety of Neurontin for off-label use. The court rejects the defendants' argument that King's testimony will be unduly prejudicial.

Second, the court finds that King's methodology is acceptable. The defendants claim that King reaches his conclusions by mere *ipse dixit* and that he employs no ascertainable methodology at all. But a review of King's report shows that, in explaining the characteristics of the prescription drug marketplace, he relies on and frequently cites scholarly articles and studies. (*See, e.g.*, Docket No. 165, Ex. 1 ¶¶ 20-36.) Then, employing this understanding of the drug marketplace and how marketing campaigns generally influence doctors, King examines Neurontin sales data and opines on the effects of the defendants' marketing. King's conclusions are not mere "rank speculation," (Docket No. 119 at 9), despite the fact that he did not interview individual doctors to determine why they personally prescribed Neurontin.

The defendants argue that King failed to consider any other explanations for the increase in the percentage of off-label prescriptions. (Docket No. 119 at 6-8.) But King only concludes that the marketing campaign was a "significant contributing factor[]" to off-label sales. (Docket No. 165, Ex. 1 ¶ 103.) This implicitly acknowledges that other factors also influenced the growth; indeed, King expressly acknowledges that one study found the existence of strong clinical support for approximately 20% of off-label Neurontin usage. (*See id.* ¶ 18.) The defendants can address the relative magnitude of other potential factors in cross-examination. In sum, the court finds that, because King reviewed relevant academic literature to gain a

framework to analyze the defendants' marketing campaign, he employed methods "similar to those commonly used in refereed academic publications undertaking similar analysis." (Docket No. 165, Ex. 2 ¶ 4.)

The defendants also argue that the plaintiff's attorneys exercised too much influence over King, largely because the charts in King's report were created by an outside firm hired by the attorneys. (Docket No. 119 at 9-10.) But nothing indicates that King did not adequately review or verify this work. *See In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 963 (D. Minn. 2009) (refusing to exclude expert testimony, even though a chart was prepared by plaintiff's counsel, because the expert reviewed "voluminous materials prior to reaching her conclusion" and because there was no indication that the chart "was incapable of verification or meaningful review"). This does not provide a basis for excluding King's testimony.

Finally, the defendants argue that King's testimony regarding his interpretation of documents and regarding the defendants' motive or intent will improperly usurp the role of the jury. (Docket No. 119 at 10-15.) King may properly testify as to his interpretation of internal marketing-related documents that he relied on in forming his opinions. *See In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769, 2009 WL 3806436, at *4 (M.D. Fla. July 20, 2009) (holding that expert witnesses may "rely on and discuss [the defendant's] internal corporate documents . . . . To rule otherwise would unduly restrict Plaintiffs' experts from explaining the bases of their opinions."). He may not, however, testify as to the defendants' motives or intent. *Id.* The defendants highlight instances of arguably objectionable portions of King's testimony in previous MDL cases. (*See* Docket No. 119 at 11, 11 n.12.) But King's statement, which has

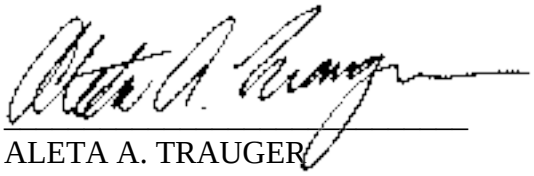
been filed with the court and will constitute his direct testimony in this case, does not contain any speculation regarding the defendants' motives or intent. (*See* Docket No. 180, Ex. 6.) The court notes that the defendants may object at trial if they believe that King's testimony, outside of his statement, improperly discusses motive or intent.

Accordingly, the defendants' motion will be denied.

CONCLUSION

For all of the reasons discussed above, the court will deny the above-listed motions *in limine*.

An appropriate order will enter.



ALETA A. TRAUGER
United States District Judge